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Bill J. Pope

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EXAMINER

WALKER, AMANDA H

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/727,908	Applicant(s) POPE ET AL.	
	Examiner AMANDA H. WALKER	Art Unit 3774	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 November 2004 and 13 December 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 29-67 is/are pending in the application.
- 4a) Of the above claim(s) 30,31,46,47,51,54 and 67 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 29,32-45,48-50,52,53 and 55-66 is/are rejected.
- 7) ☒ Claim(s) 36 and 65 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION***Election/Restrictions***

Applicant's election of species 1(a), 1a(ii), 2(b), 3(b), 4(a), 5(b), 6(b), 7(b), 8(b), and 10(f) (claims 29, 32-45, 48-50, 52, 53, and 55-66) in the reply filed on 12-13-07 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 30, 31, 46, 47, 54, and 67 were withdrawn by Applicant. With regards to species 7(b), claim 51 will also be withdrawn. Species 7(b) relates to a substrate/table interface which does not contain a third material. Claim 51 claims a substrate having two distinct substrate layers of different materials. The substrate/table interface would inevitably contain a third material, which was species 7(a).

The restriction requirement with regards to Species 9a, 9b, and 9c has been withdrawn since the relevant claims are product-by-process related.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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Claims 29, 32-45, 48, 49, and 52-55 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

These claims are indefinite because in claim 29, it is unclear as to whether the load bearing portion and the substrate are actually one continuous material or actually separate entities. For the purpose of further examination, the Office interprets them to be one continuous material, since priority will then go back to the 1994 date instead of the 1999 date.

Claim 40 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 40 recites the limitation "said polycrystalline diamond load bearing...surface" in lines 1-2. There is insufficient antecedent basis for this limitation in the claim.

Claim 55 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 55 recites the limitation "said first joint member...counter bearing material" in lines 1-2. There is insufficient antecedent basis for this limitation in the claim.

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Claims 56-66 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Lines 12 and 13 cite a volume of diamond located on a load bearing portion. However, they do not state which load bearing portion (that of the first joint member or the second joint member).

Claims 57-65 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

These claims are indefinite because in claim 57, it is unclear as to whether the load bearing portion (the external surface of the joint member) and the substrate are actually one continuous material or actually separate entities. For the purpose of further examination, the Office interprets them to be one continuous material, since priority will then go back to the 1994 date instead of the 1999 date.

Claim Objections

Claim 36 is objected to because of the following informalities: “residual stress field said” appears to be a typo. For the purpose of further examination, the Office interprets “residual stress field said” to mean –residual stress field on said--. Appropriate correction is required.

Claim 65 is objected to because of the following informalities: the comma after "wherein Mcd," appears to be a typo. Appropriate correction is required.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 29, 32-42, 48-50, 52, 53, and 55-66 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dearnaley et al. (United States Patent Number 5,593,719) in view of Dennis (United States Patent Number 5,120,327), as evidenced by Lewin et al. (United States Patent Number 4,486,286).

Regarding Claims 29, 56, and 57: Dearnaley et al. teaches a method of modifying surfaces made from metal alloy or ultra high molecular weight polyethylene (UHMWPE) for use in orthopedic implants such as the knee (1:35-45). The joint capable of being used as a knee implant includes a first joint member/hemispherical socket (1:35-45), a first joint member bone fixation portion (1:54-57), and a first joint member load bearing portion (1:55-57). Dearnaley et al. also teaches a second joint member/more-or-less spherical ball (1:35-40), a second joint member bone fixation portion/stem (1:50-55), and a second joint

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member load bearing portion (3:45-60). The second joint member load bearing portion is made of a diamond-like compact (3:55-60). The diamond-like compact has two components: 1) a substrate made of metal alloy (5:10-15) coated with silicon to create a metal-silicide interface, and 2) a table of diamond-like carbon chemically bonded to the other side of the metal-silicide interface, forming silicon-carbide bonds (10:15-20). This provides a smooth and low friction load bearing surface. However, Dearnaley et al. does not teach using a compact with actual sintered polycrystalline.

Dennis teaches a compact having polycrystalline diamond for use in cutting elements. Polycrystalline diamond is sintered to a metal (cobalt) cemented carbide (1:10-30 and 3:35-55), which is then brazed to a stud (1:10-20). The compact comprises the carbide and the polycrystalline diamond surface. The stud taught by Dennis is analogous to the joint taught by Dearnaley et al., the carbide substrate taught by Dennis is analogous to the silicon coated metal surface taught by Dearnaley et al., and the outer polycrystalline diamond surface taught by Dennis is analogous to the diamond-like carbon taught by Dearnaley et al. Dearnaley et al. and Dennis are combinable because they are concerned with the same technical difficulty, namely, providing wear-resistant surfaces at high-friction interfaces. At the time of the invention, it would have been obvious to a person having ordinary skill in the art to modify the diamond-like carbon compact on the load bearing surface of the joint taught by Dearnaley et al. with the polycrystalline diamond compact taught by Dennis, and one would have been motivated to do so because the use of real diamond would have been obvious

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alternative in light of the suggestion of a “diamond-like” surface as taught by Dearnaley et al. Benefits of using diamond or diamond-like materials in orthopedic applications are hardness, chemical inertness, and good insulating properties which diminish chances of clotting (Lewin et al., 1:10-35).

Regarding Claims 32, 59, and 62: The compact taught by Dearnaley et al. has chemical bonds between the diamond-like carbon table and the metal-silicon substrate (10:15-20). Furthermore, Dennis teaches a compact comprising a cobalt-cemented carbide substrate sintered to a polycrystalline diamond table. While Dennis does not specifically mention the chemical bonds that occur between the cobalt and the diamond, they are assumed to be inherently present since the materials and process of making the compact are the same as that of the instant application (instant application, para. 0143).

Regarding Claims 33, 34, 60, and 61: The compact taught by Dennis comprises a mechanical grip between the diamond table and the substrate that is made possible by topographical features (FIG. 1).

Regarding Claim 35: The articulation surface taught by Dearnaley et al. is convex and partially spherical (1:35-40 and 3:45-55).

Regarding Claims 36 and 63: A residual stress field is inherent to a crystalline material such as the polycrystalline diamond used in Dennis. Nonetheless, Dennis also mentions a residual stress field in the compact (4:10-15).

Regarding Claims 37 and 64: Different coefficients of thermal expansion are inherent to the diamond/diamond-like carbon and substrates of both

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Dearnaley et al. and Dennis, considering that any two different materials are going to have different expansion properties.

Regarding Claims 38 and 65: Different moduli are inherent to the diamond/diamond-like carbon and substrates of both Dearnaley et al. and Dennis, considering that any two different materials are going to have different mechanical properties.

Regarding Claims 39 and 66: Dearnaley et al. teaches that the Ra value of the load bearing and articulation surface is less than 0 to 0.05 micrometers Ra (8:30-35).

Regarding Claim 40: The property of being “burnished” is inherent to both the teachings of Dearnaley et al. and Dennis, considering that they are used in high-friction environments. They become burnished with wear.

Regarding Claim 41: The “stem” and the “cup” taught by Dearnaley et al. are inherently shaped to be press fit into a receptacle formed in bone (1:45-60), and inherently have “bone mating” portions. Any surface which touches bone is considered a “bone mating” portion.

Regarding Claim 48: The metal-silicon substrate taught by Dearnaley et al. may include cobalt, titanium, tungsten, or molybdenum (5:10-15).

Regarding Claims 49 and 58: The substrate taught by Dearnaley et al. includes metal cemented carbide (the silicon carbide [SiC] bonds are cemented to the metal substrate underneath) (10:15-20). Furthermore, Dennis also teaches a metal (cobalt) cemented carbide (1:10-30 and 3:35-55). The cobalt “weeps” out

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of the carbide underneath to inherently form a gradient zone between the polycrystalline diamond and the substrate (3:35-55).

Regarding Claim 50: The metal silicon substrate taught by Dearnaley et al. teaches a plurality of layers (metal of the joint component, then silicon) (5:1-10). The substrate taught by Dennis also has a plurality of layers (metal of the stud, then tungsten/cobalt) (1:10-20).

Regarding Claim 52: Dennis teaches the use of varying sizes of diamond crystals (5:5-10).

Regarding Claims 53 and 55: Dearnaley et al. teaches that the first joint member has a counter bearing material, UHMWPE, against which the diamond-like carbon table articulates. UHMWPE is not as hard as the diamond-like carbon table (3:45-60).

Claims 43-45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dearnaley et al. (United States Patent Number 5,593,719) in view of Dennis (United States Patent Number 5,120,327), as evidenced by Lewin et al. (United States Patent Number 4,486,286) as applied to claim 29 above, and further in view of Kenna (United States Patent Number 4,550,448).

Dearnaley et al. teaches the basic bone fixation/mating surfaces as applied above. However, Dearnaley et al. does describe the construction of the implant sufficiently to teach specific features of the bone mating surface on the bone fixation portions.

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Kenna teaches a knee prosthesis (FIGS. 1-4) coated with metal sintered beads (FIG. 2 and abstract). This feature will inherently enhance frictional engagement with the bone as well as encourage bone ingrowth (abstract). Dearnaley et al. and Kenna are combinable because they are from the same field of endeavor, namely, knee implants. At the time of the invention, it would have been obvious to a person having ordinary skill in the art to modify the bone fixation surfaces of the implant taught by Dearnaley et al. with the sintered metal beads as taught by Kenna, and one would have been motivated to do so in order to lock the prosthesis in place (Kenna, 1:10-15).

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

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Claims 29, 32-45, 48, and 50-52 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-3, 11-13, 15-19, 21, 22, 24, and 26-28 of U.S. Patent No. 7,077,867. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims are broader in scope than the previously patented claims.

Claims 29, 49, 53, and 55 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 37, 48, 52, and 54 of U.S. Patent No. 7,077,867. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims are broader in scope than the previously patented claims.

Claims 56-64 and 66 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 55-62 and 65 of U.S. Patent No. 7,077,867. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims are broader in scope than the previously patented claims.

Claims 56-63 and 65 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 64 of U.S. Patent No. 7,077,867. Although the conflicting claims are not identical, they are

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not patentably distinct from each other because the instant claims are broader in scope than the previously patented claim.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to AMANDA H. WALKER whose telephone number is (571)270-3296. The examiner can normally be reached on 8-5, M-Th, EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571) 272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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/Alvin J Stewart/
Primary Examiner, Art Unit 3774

AHW
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